

### **REMARKS**

The Office Action rejected claims 1-4, 6-9, 15-20, 22-25, 30-40 and 44-52. Claims 5, 10-14, 21, 26-29 and 41-43 were previously canceled. By this Amendment, to expedite prosecution of this application, claims 1, 6, 22, 30, 35-36, 40, 44, 49-50 and 52 are amended, claim 15 is cancelled, and claim 53 is added. No new matter has been presented. Claims 1-4, 6-9, 16-20, 22-25, 30-40 and 40-53 are currently pending in this application.

### **Interview Summary**

The Applicants thanks Examiner Kahelin for his participation in a telephone interview with Catherine Spolar on October 25, 2010. In general, the participants discussed the scope of the claimed subject matter. No agreement was reached.

### **Claim Objections**

The Office action objected to claim 6 for informalities. Appropriate correction to claim 6 has been made. Withdrawal of the rejection is respectfully requested.

### **Claim Amendments**

Independent claim 1 has been amended to clarify that the first and second layers comprise an insulative polymer, and that the third layer consists of a drug. Claim 35 has been amended in a similar manner to claim 1. Claim 16 has been amended to recite that the coating is disposed on a portion of the electrode to define coated and uncoated portions of the electrode. Claim 30 has been amended to recite that the inner layer includes a pharmacological agent dispersed within an insulative polymer matrix, and that the outer layer consists of a drug. Support for the amendments to claims 1, 16, 30 and 35 can be found in paragraphs [0014]-[0022] of the Applicants' specification and in FIG. 4. New claim 53 recites that the insulative polymeric base material is selected from a group of polymers disclosed in the specification as originally filed.

### **Section 112 Rejections**

The Office action rejected claims 1-4, 6-9, 15-20, 22-25, 30-40 and 44-52 under 35 U.S.C. § 112, second paragraph. With respect to claims 1, 16, 30 and 35, the Examiner sought clarity as to the scope of the "consisting of" limitation. Applicants do not dispute the Examiner's

interpretation of the “consisting of” language used in the claims as excluding a polymer matrix, but may include excipients.

Claims 6, 22 and 36 have been amended to recite that the drug is any one of an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent or an antiproliferative agent. Claim 35 has been amended to recite the step of coating the first layer of the electrode with a second layer, wherein the second layer comprises an insulative polymer and at least a first pharmacological agent.

The Applicants respectfully submit that the claims, as listed above, fully satisfy the requirements of 35 U.S.C. § 112. Reconsideration and withdrawal of the rejection is respectfully requested.

### **Section 103 Rejections**

The Office action rejected claims 1-4, 6-9, 15-20, 22-25, 30-40, 44, and 45 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,964,794 (“Bolz”) in view of U.S. Patent 4,506,680 (“Stokes”).

The Office Action asserts that Bolz discloses an electrode (FIG. 8, 1a) including a first layer comprising an insulative material adjacent the surface of the electrode (1b” closest to 1a), a second layer (second 1b”) layer from 1a) including at least one pharmacological agent (1c) disposed over the first layer and a third layer (third 1b”) from 1a) disposed over the second layer including at least one pharmacological agent. The Office Action admits that Bolz does not teach that the third layer consists of a drug, and instead relies on Stokes for teaching that it is well known to coat drug eluting leads with a an outer layer consisting of a pharmacological agent.

The combination of Bolz and Stokes fails to teach or suggest each and every limitation of the invention recited in claims 1, 16, 30 and 35 at least because neither reference discloses or suggests a base layer comprising an insulative material. Further, there would have been no reasonable basis to modify the electrode coating of Bolz with a drug/water/alcohol solution as disclosed by Stokes to provide a top or outer layer consisting of a drug as recited by claims 1, 16, 30 and 35.

Contrary to the Office Action’s assertion, Bolz does not disclose an insulative polymer coating or coating layer. Bolz expressly discloses a coating specifically intended to obtain a

“high phase boundary capacitance and hence low electrical impedance.” (Bolz, Col. 2, lines 5-10).

In support of its assertion that Bolz discloses an insulative polymer layer, the Office Action relies on a statement in Bolz that the coating illustrated in Fig. 8 is “a relatively thick polyelectric multilayer with a high dielectric constant.” (Bolz, col. 9, lines 20-27).

It is well known that polyelectrolyte multilayer include alternating layers of negatively and positively charged polyelectrolytes, and are designed to promote conductivity rather than to act as an insulator. In the method described by Bolz, poly(styrene) sulfonate sodium salt is applied first to the electrode surface and thus, is the inner or first layer (1b” closest to 1a).. Poly(styrene) sulfonate sodium salt is a polyelectrolyte and an ionomer. Ionomers have unique physical properties *including electrical conductivity*.

Moreover, the mere fact that a polymer coating has a high dielectric constant does not necessarily mean that the coating possesses insulative properties. Indeed, Bolz expressly states that a high dielectric constant is preferred “[t]o assure advantageous electrical properties and especially little influence on the high phase-boundary capacitance of highly sophisticated stimulation electrodes.” (Col. 2, lines 30-39). This statement directly contradicts the assertion that a coating with a high dielectric constant is necessarily insulative. Further, Bolz teaches that the coating *reduces impedance*, and has a markedly positive effect on the course of the stimulation threshold (Bolz, abstract, and col. 7, lines 6-65). This could not be achieved by applying an insulative material over the entire outer surface of the electrode as taught by Bolz.

For the same reason, Bolz does not teach, disclose or suggest a coating including a second or inner layer comprising an insulative polymer or polymer matrix material and a first pharmacological agent as recited by claims 1, 16, 30 and 35. Rather, Bolz teaches that an active ingredient 1c can be incorporated into the polyelectrolyte multilayer, which as discussed above, is not an insulative polymer.

For these reasons alone, the obviousness rejection of claims 1, 16, 30, 35 and all claims depending therefrom should be withdrawn.

Moreover, as admitted by the Office Action, Bolz does not teach or suggest a coating including a third or outer layer consisting of a drug as recited by the claimed invention. Instead, the Office Action relies on Stokes for teaching that it is well known to coat drug-eluting leads with an outer layer consisting of a pharmacological agent.

Stokes discloses that it is desirable to wet a porous tip electrode with a drug solution prior to implantation. Even assuming that dipping an electrode in a drug solution is known, it would not necessarily be reasonable to dip an electrode comprising the coating disclosed in Bolz with such a drug solution. Notably, dipping a polyelectrolyte multilayer coating as taught by Bolz into a solution including a drug dissolved in water and alcohol would likely cause the individual polyelectrolyte layers to swell and/or release drug prior to implanting the lead into a patient. As such, one of skill in the art would have no reason to risk applying the drug/water/alcohol solution as taught by Stokes to the polyelectrolyte multilayer coated electrode as taught by Bolz prior to implantation.

The combination of Bolz and Stokes fails to teach or suggest each and every limitation of the claimed invention as recited by claims 1, 16, 30 and 35. Further, there is no basis to modify the electrode of Bolz with the drug/water/alcohol solution by Stokes in attempt to arrive at the claimed invention as recited by claims 1, 16, 30 and 35. Claims 1, 16, 30 and 35 are patentable over the combination of Bolz and Stokes. Dependent claims 2-4, 6-9, 17-20, 22-25, 31-34, 36-40, 44 and 45 are also patentable for at least those same reasons as discussed above. Withdrawal of the rejection is respectfully requested.

Claims 9, 25, 30, 39 and 40

Independent claim 30 further recites that the coating includes a middle layer disposed between the inner layer and the outer layer, wherein the middle layer includes a porous polymer barrier and is adjacent to and in contact with the inner layer and not adjacent to the surface of the electrode. Dependent claims 9, 25, 39 and 40 also recite that the coating includes an additional fourth layer comprising a porous polymeric barrier.

The Office Action asserts that the electrode as taught by Bolz includes a porous polymeric fourth layer because FIG. 8 shows that the drug molecules from the lower layers can escape and this layer regulates their escape and is polymeric. Applicants disagree at least for the reasons discussed above.

Moreover, Bolz merely discloses that the departure of the active ingredient from the organic layer is diffusion controlled. Diffusion can be controlled via variety of processes and/or gradients including concentration gradients, potential gradients, etc. Bolz does not teach, disclose or suggest that any of the individual layers forming the polyelectrolyte multilayer is a

porous polymeric layer having a porosity sufficient to regulate a release of a pharmacological agent an underlying layer.

Withdrawal of the rejection with respect to claims 9, 25, 35, 39 and 40 is respectfully requested.

Claims 2, 4, 7, 8, 14, 17, 19, 20, 23, 31, 34, 38 and 45

With respect to the Examiner's assertion that the Applicants failed to traverse the taking of Official Notice with regards to the claims listed above in the Office Action of April 21, 2010, the Applicants note that the Examiner *never stated that he was taking Official Notice*. If that was the Examiner's intent, then he not only should have expressly made such a statement he should have produced documentation or pointed to specific passages in the alleged prior art to support his position in order to establish a *prima facie* case of obviousness. The Examiner cannot for the first time take the position that his previously unsupported and conclusory statements constituted an Official Notice and at the same time contend that Applicants alleged silence constitutes an admission.

Moreover, the Applicants direct the Examiner to the second paragraph, last sentence in Applicants conclusion of the response filed on July 14, 2010, in which the Applicants state that "even if not expressly discussed above, the applicant respectfully traverses each of the rejections, assertions, and characterizations regarding the disclosure and teachings of the cited references, including the prior art status and the propriety of proposed combinations of cited references." Thus, the Examiner's alleged taking of Official Notice in the Office Action of April 10, 2010 was expressly traversed.

Moreover, claims 2, 4, 7, 8, 14, 17, 19, 20, 23, 31, 34, 38 and 45 depend from claims 1, 16, 30 and 35, respectively, they are also patentable for at least those same reasons as discussed above. Withdrawal of the rejection is respectfully requested.

Claims 46, 48 and 51

Claims 46, 48 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolz and Stokes as applied to claims 1, 16 and 35 discussed above, and further in view of U.S. Patent 5,103,837 ("Weidlich").

Claims 46, 48 and 51 depend from claims 1, 16 and 35, respectively, and thus are also patentable for at least those same reasons as discussed above. Weidlich fails to remedy the deficiencies of the combination of Bolz and Stokes in arriving at the claimed invention. Weidlich discloses a single layer coating disposed over a porous electrode including an anti-inflammatory agent embedded within a hydrophilic polymer and teaches nothing relevant to the multi-layered drug eluting coating as recited by the claimed invention. Withdrawal of the rejection is respectfully requested.

#### Claim 50

Claim 50 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolz and Stokes, as applied to claim 30 above, and further in view of U.S. Patent 7,187,980 (“Osypka”).

Claim 50 depends from claim 30 and thus, is also patentable for at least those same reasons as discussed above. Moreover, Osypka fails to remedy the deficiencies of Bolz and Stokes, discussed above, in arriving at the claimed invention. Osypka discloses a steroid eluting ring located on a lead body proximal to the electrode and not a multi-layered coating disposed on an electrode. Additionally, Osypka discloses a single layer coating and teaches nothing relevant to the multi-layered drug eluting coating as recited by the claimed invention. Withdrawal of the rejection is respectfully requested.

#### Claims 47, 49 and 52

Claims 47, 49 and 52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolz, Stokes, and Weidlich, as applied to claims 46, 48 and 51 above, and further in view of U.S. Patent 7,187,980 (“Osypka”).

Claims 47, 49 and 52 depend indirectly from claims 1, 16 and 35, respectively, and thus, are also patentable for at least those same reasons as discussed above. Osypka, directed to a steroid eluting collar, fails to remedy the deficiencies of Bolz, Stokes and Weidlich, discussed above, in arriving at the claimed invention. Withdrawal of the rejection is respectfully requested.

#### New Claim 53

New claim 53 recites that the insulative polymeric material can be selected from the group consisting of Parylene, polyurethanes, polyacrylates, polymethacrylates, polyamides,

polyethers, polysiloxanes, and polyepoxy resins. Support for new claim 53 can be found in paragraph [0016] of the Applicants specification. No new matter has been entered.

New claim 53 depends from claim 1, and is also patentable for at least those same reasons as discussed above.

**Conclusion**

For the reasons explained above, all pending claims are now in condition for allowance. Accordingly, the applicant respectfully requests that the Office issue a Notice of Allowance.

Any amendments to the claims are made to expedite prosecution of this application, without acquiescing to the Office's rejections or characterizations of the claims or references in the Office Action: Any claim amendments not specifically discussed or explained in the above remarks are not made for patentability purposes, and these claims would satisfy the statutory requirements for patentability without these amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, or to reduce the time and effort required of those skilled in the art to clearly understand the scope of the claim language. Even if not expressly discussed above, the applicant respectfully traverses each of the rejections, assertions, and characterizations regarding the disclosure and teachings of the cited references, including the prior art status and the propriety of proposed combinations of cited references.

The applicant has made a good faith effort to respond to all rejections set forth in the Office Action and to place the pending claims in condition for immediate allowance. If the Examiner has any questions or comments, the Examiner is requested to contact the undersigned at 612-766-8245.

Respectfully submitted,

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Dated: November 16, 2010

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